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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,317	08/21/2006	Christof Westenfelder	38447-201N01US	6531

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
09/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,317	WESTENFELDER, CHRISTOF	
	Examiner	Art Unit	
	ANNE MARIE S. WEHBE	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,4,6-9,11-18,49,50,60 and 61* is/are pending in the application.

5a) Of the above claim(s) *4 and 11-18* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,6-9,49,50,60 and 61* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/11 has been entered.

Applicant's amendment and response received with the 8/9/11 RCE have also been entered. Claims 3, 5, 10, 19-48, and 51-59 are now canceled, and new claim 61 has been added. Claims 1-2, 4, 6-9, 11-18, 49-50, and 60-61 are currently pending in the instant application. Of these, claims 4 and 11-18 remain withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to a non-elected invention, there being no allowable generic or linking claim. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 1-2, 6-9, 49-50, and 60-61 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 102

The rejection of previously pending claims 1-2, 6-10, 49-50, and 60 under 35 U.S.C. 102(a) as being anticipated by Imai et al. (2002) Ped. Nephrol., Vol. 17, 790-794, is withdrawn over canceled claim 10, and further withdrawn over the remaining claims in view of

applicant's amendments to introduce the limitation that the mesenchymal stem cells have been expanded *in vitro* to produce an enriched population of mesenchymal stem cells.

The rejection of claims 51-52 under 35 U.S.C. 102(a) as being anticipated by WO 03/13588 (2/24/03), hereafter referred to as Tabata et al., and the rejection of claims 51-52 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,486,359 (1999), hereafter referred to as Caplan et al., are both withdrawn in view of the cancellation of claims 51-52.

Applicant's amendments to the claims has necessitated the following new grounds of rejection under 35 U.S.C. 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6-9, 49-50, and 60-61 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2004/0258670 (2004), hereafter referred to as Laughlin et al. Note that Laughlin et al. has an effective filing date of 12/5/02.

Laughlin et al. teaches methods of treating renal ischemia comprising administering to a patient in need thereof enriched human mesenchymal stem cells and enriched endothelial generating cells (Laughlin et al., claims 1 and 36, and paragraphs 41, 43-44, and 86-87). Note

that renal ischemia is an acute kidney dysfunction. Laughlin et al. further teaches that the endothelial generating cells are hematopoietic stem cells, and that the human mesenchymal stem cells are either autologous or allogeneic bone marrow derived human mesenchymal stem cells (Laughlin et al., claims 16-17 and 21-22, and paragraphs 41 and 44). Laughlin et al. also teaches that the human mesenchymal stem cells and endothelial generating cells are administered in a ratio from about 5:1 to about 1:5 (Laughlin et al., claim 28, and paragraphs 44 and 81). In addition, Laughlin et al. teaches that enriched human mesenchymal stem cells can be generated by differential adhesion separation, where bone marrow or peripheral blood cells are grown in media that stimulates mesenchymal stem cells growth without differentiation and selection of the adherent cell population results in a highly purified culture of adherent mesenchymal stem cells (Laughlin et al., paragraphs 75-77). Laughlin et al. further teaches to genetically modify the mesenchymal stem cells prior to their administration to the subject (Laughlin et al., paragraph 78). Finally, Laughlin et al. teaches that about 1X10-4 cells/kg to about 7x10-5 cells/kg of mesenchymal stem cells are administered to the subject to be treated (Laughlin et al., paragraph 81). Thus, by teaching all the limitations of the claims as written, Laughlin et al. anticipates the instant invention as claimed.

It is acknowledged that the applicant has submitted a Declaration under 37 CFR 1.132 by Robert Brenner, who is not an inventor of the instant methods. The Declaration has been fully considered. The Declaration concerns the rejection of certain claims under 102(a) over Imai et al. and states that anti-Thy1 antibody mediated glomerulonephritis is not an acute kidney dysfunction. However, as noted above, the rejection over Imai et al. has been withdrawn in view

of applicant's amendments to the claims and thus the evidence of the Brenner Declaration is moot is regards to the withdrawn rejection. Further, the statements in the Declaration do not apply to the new grounds of rejection over Laughlin et al. since Laughlin et al. teaches the treatment of renal ischemia. Note that the Brenner Declaration states that ischemic kidney injury is a model of acute kidney dysfunction.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633